

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Heid and Livak

Serial No.: To be assigned

Filed: March 15, 2002 (herewith)

For: **EXTERNAL CONTROL REAGENTS  
FOR NUCLEIC ACID AMPLIFICATION**

Group Art Unit: 1656

Examiner: Tung, J.

CERTIFICATE OF EXPRESS MAILING

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11002 U.S. PTO  
10/099738



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (listed on the attached Form PTO-1449) of which they are aware, which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement:

(a) ☒ accompanies a new patent application submitted herewith.

(b) ☐ is filed within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491.

(c) ☐ as far as is known to the undersigned, is filed before the mailing date of a first Office action on the merits.

- (d) ☐ as far as is known to the undersigned, is filed before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114.
- (e) ☐ is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final action under § 1.113, a notice of allowance under § 1.311, whichever occurs first, and is accompanied by either the fee (\$180) set forth in 37 CFR § 1.17(p) or a certification as specified in 37 CFR § 1.97(e), as checked below. Should any fee be due, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 01-2213 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account. **A duplicate of this sheet is enclosed.**
- (f) ☐ is filed after the mailing date of either a final rejection or a notice of allowance, but on or before the payment of the issue fee, and is accompanied by the fee (\$180) set forth in 37 CFR § 1.17(i)(1) **and** a certification as specified in 37 CFR § 1.97(e), as checked below. **This document is to be considered as a petition requesting consideration of the information disclosure statement.** The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 01-2213 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account. **A duplicate of this sheet is enclosed.**

[If either of boxes (e) or (f) is checked above, the following "certification" under 37 CFR § 1.97(e) may need to be completed.] The undersigned certifies that:

- ☐ Each item of information contained in the information disclosure statement was first cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this information disclosure statement.

A copy of the items on PTO-1449 is supplied herewith:

☐ each ☒ none ☐ only those listed below:

Those patent(s) or publication(s) listed in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/645,959, filed August 24, 2000 and relied upon in this application for an earlier filing date under 35 USC §120.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR §1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR §1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR §1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR §1.98 and MPEP §609 and the Examiner is respectfully requested to consider the listed references.

Respectfully submitted,

Date: March 14, 2002



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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	2		

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	05	COEN, Donald M., "Quantification of DNAs by the Polymerase Chain Reaction Using an Internal Control, 'The Polymerase Chain Reaction'" pp. 89-96 (1994).	
	06	COREY, E. et al., "Improved Reverse Transcriptase-Polymerase Chain Reaction Protocol with Exogenous Internal Competitive Control for Prostate-Specific Antigen mRNA in Blood and Bone Marrow," <i>Clinical Chemistry</i> , 43:3, pp. 443-452 (1997).	
	07	GIBSON, et al., "A Novel Method for Real Time Quantitative RT-PCR," <i>Genome Research</i> , 6:995-1001 (1996).	
	08	GILLES, et al., "Single Nucleotide Polymorphic Discrimination by an Electronic Dot Blot Assay on Semiconductor Microchips," <i>Nature Biotechnology</i> , Vol. 17, pp. 365-370 (1999).	
	09	HEID, et al., "Real Time Quantitative PCR," <i>Genome Research</i> , 6:986-994 (1996).	
	10	LIVAK, Kenneth J., "Allelic Discrimination Using Fluorogenic Probes and the 5' Nuclease Assay," <i>Genetic Analysis: Biomolecular Engineering</i> , 14:143-149 (1999).	
	11	REISCHL, et al., "Quantitative PCR A Survey of the Present Technology," <i>Molecular Biotechnology</i> , Vol. 3, pp. 55-71 (1995).	
	12	"Primer Express Version 1.5 and TaqMan MGB Probes for Allelic Discrimination," <i>User Bulletin</i> , Applied Biosystems, pp. 1-28, May 26, 2000.	
	13	"TaqMan® Allelic Discrimination Demonstration Kit," <i>Protocol</i> , PE Applied Biosystems, pp. 1-35 (1998).	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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